

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

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The Office Action:

- a) rejected claim 18 under 35 USC §112, Second Paragraph; and
- b) rejected claims 1 – 5, 7 – 12, and 15 - 23 under 35 USC §103 as being unpatentable over United States Patent No. 6,432,442 to Buehler, et al. ("Buehler") in view of United States Patent No. 5,075,112 to Roche, et al. ("Roche"), in view of United States Patent No. 5,532,244 to Wong, et al. ("Wong"), and further in view of United States Patent No. 5,789,393 to Dressman, et al. ("Dressman").

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Claims 1 – 5, 7 – 12, and 15 - 23 remain pending in this application after entry of this response.

I. The rejection of claim 18 under 35 USC §112, Second Paragraph should be withdrawn.

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Claim 18 stands rejected under 35 USC §112, second paragraph, as allegedly lacking antecedent basis. Applicant respectfully disagrees for the reasons that follow.

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Claim 18, which depends from claim 9 and incorporates all of its limitations therein, provides that the "hydroxyalkylcellulose is hydroxypropylcellulose and/or hydroxypropylmethylcellulose."

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Claim 9, which is dependent upon claim 8 and incorporates all of its limitations therein, is directed to the "dosage form of claim 8" and further defines one embodiment of the taste masking coating.

Claim 8, which is dependent upon claim 1 and incorporates all of its limitations therein, is directed to the "dosage form of claim 1" and further defines that:

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the dosage form is comprised of, based upon the total weight of the dosage form,

- a) from greater than about 0.25 percent and less than about 70 percent of the coated particles comprising the pharmaceutically active ingredient, said coated particles comprising, based upon the total weight of the coated particles, from greater than about 1 percent and less than about 50 percent of the taste masking coating; and
 - b) from greater than about 0.5 percent and less than about 10 percent of the *hydroxyalkylcellulose* in the matrix.

(emphasis added) Applicants respectfully submit that not only is there antecedent basis for “hydroxalkylcellulose” in claim 8, but also all of the elements of claim 8 are incorporated by claim 9, which is dependent upon claim 8. Therefore, it is clearly evident that there is antecedent support for “hydroxalkylcellulose” in claim 18 because: 1) claim 18 is dependent upon claim 9; 2) claim 9 is dependent upon claim 8; and 3) dependent claims incorporate all of the limitations of the claims to which they depend. Applicants further respectfully submits that that the rejection of claim 18 under 35 USC §112, second paragraph, has been overcome and should be withdrawn.

II. The rejection of claims 1 – 5, 7 – 12, and 15 - 23 under 35 USC §103 as being unpatentable over Buehler in view of Roche, in view of Wong and further in view of Dressman should be withdrawn.

Claims 1 – 5, 7 – 12, and 15 - 23 stand rejected under 35 USC §103 as being unpatentable over Buehler in view of Roche, in view of Wong, and further in view of Dressman. Applicant respectfully disagrees for the reasons that follow.

Buehler discloses "a chewable, gelatin based matrix which contains pharmaceutical active ingredients.... In preferred embodiments of the invention, hydrocolloid ingredients are added to the gelatin matrix." Buehler, column 2, lines 23 – 31. Buehler then lists several suitable hydrocolloids, one of which could be hydroxypropyl cellulose ("HPC"). However, Buehler fails to disclose or suggest the particular hydroxyalkylcellulose as claimed in claim 1 in its matrix:

a hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 and/or a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution,

5 (emphasis added).

Roche discloses particles, which "are coated with a blend of [cellulose acetate] CA and/or [cellulose acetate butyrate] CAB and [hydroxypropyl cellulose] HPC, which then can be] compressed into tablet form. Roche column 2, lines 21 – 37 (emphasis added).

10 However, Roche fails to disclose or suggest the use of a hydroxyalkylcellulose in the dosage form matrix as claimed herein.

15 According to the Office Action, "Wong is only used to show that HPMCP [is] an obvious derivative of HPC." Applicants respectfully request that the Examiner point to the location in Wong that supports that statement. Nonetheless, even if Wong discloses HPMCP (hydroxypropylmethylcellulose phthalate) as an enteric coating as proposed in the Office Action, Applicants respectfully submit that Wong still fails to disclose or suggest the use of a hydroxyalkylcellulose in the dosage form matrix as claimed herein.

20 Dressman discloses the use of certain "high viscosity grade cellulose ether[s]" as the "active ingredient" in its dosage form. See column 31, lines 58 – column 32, line 7. However, Dressman fails to disclose or suggest the use of such cellulose ethers in the matrix of a dosage form. Moreover, Dressman further fails to disclose or suggest the use of cellulose ethers in the matrix of a dosage form, wherein such dosage form also contains "a plurality of particles comprising a pharmaceutically active ingredient."

25 Therefore, even if one were to combine all of the cited prior art as proposed in the Office Action, the resulting combination would still lack the particular claimed hydroxyalkylcellulose (i.e., "hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 and/or a viscosity of from about 3,000 mPa.S to about 150,000 mPa.s in a 2% aqueous solution") in the matrix of the dosage form. (emphasis added) Therefore, Applicants respectfully submit that that the rejection of claims 1 – 5, 7 – 12, and 15 - 23 under 35 USC §103 as being unpatentable over Buehler in view of Roche, in view of Wong, and further in view of Dressman has been overcome and should be withdrawn.

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Conclusion

It is submitted that the foregoing remarks place the case in condition for allowance.
A notice to that effect is earnestly solicited.

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Respectfully submitted,
Wynn, David, et al.

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